

## **REMARKS**

### **Examiner Interview**

The Applicants wish to thank Primary Examiner Salimi and Supervising Examiner Helms for the telephone conference held on September 03, 2009 regarding proposed claims 55-72. Other participants in the telephone conference included Robert Garcea, Rick Silva, David Poticha, Tara Dressler and their representative, Roberta Hanson. The interview generally consisted of discussions regarding the outstanding 102 rejections and potential amendments to overcome these rejections. No definitive agreement was reached.

### **Status of the Claims**

Claims 55-64 were pending. Claims 55, 62, 63 and 64 have been amended. Claim 59 has been canceled. New claims 65-73 have been added. No new matter has been added. Claims 55-58 and 60-73 are currently under examination.

### **Claims Amendments**

Claims 55, 62, 63 and 64 have been amended to further clarify the claims. Support for these amendments can be found throughout the application, but at least at page 2 lines 25-33, page 3 lines 1-27, page 4 lines 15-19 and 30-32; page 5 lines 1-3 and 28-29; page 7 lines 27-30; page 8, lines 17-33; page 9 lines 1-7, page 10, lines 31-33; page 11 lines 1-2; page 12 lines 1-17; page 15 lines 15-33; page 16 lines 1-22; and page 29 lines 15-25, claim 10, Table 3 and Examples 5-7 of the application as originally filed.

Claims 65-72 have been added. Support for these claims can be found throughout the application, but at least at page 2 lines 25-33, page 3 lines 1-27, page 4 lines 15-19 and 30-32; page 5 lines 1-3 and 28-29; page 7 lines 27-30; page 8, lines 17-33; page 9 lines 1-7, page 10, lines 31-33; page 11 lines 1-2; page 12 lines 1-17; page 15 lines 15-33; page 16 lines 1-22; and page 29 lines 15-25, claim 10, Table 3 and Examples 5-7 of the application as originally filed.

### **Rejection under 35 U.S.C. §102, maintained**

*§102(e)*

On page 2, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Gissman et. al (U.S. Patent no. 7,371,391 B2, [hereinafter, “Gissmann”])...”

The Applicants respectfully submit that independent claim 55 overcomes rejections based on Gissmann. Gissman recites “Vaccine formulations comprising viral capsomeres...Therapeutic and prophylactic methods of use for the vaccine formulations...” (see Abstract). The Applicants respectfully submit Gissmann fails to disclose that “one or more papillomavirus capsid L1 interaction sequence(s)” are required for complexes of the instant claims, and in particular elements of independent claim 55. In support of the claim amendments made herein, the Applicants respectfully submit Appendix A ( Finnén *et al.* J. Virol. 2003; 77:4818-4826). (see also, Chen *et al.* J. Mol. Bio. 2001: 307: 173-182 and Chen *et al.* Mol. Cell 2000; 5:557-567, and Li. *et al.* J. Virol. 1998; 72:2160-2167, attached as Appendix B). In addition, Gissman fails to disclose “the papillomavirus capsid L1 interaction sequence comprises at least 80% identity corresponding to amino acid sequence beginning with amino acid 396 and ending with amino acid 439 of SEQ ID NO: 1 or fragments thereof,” elements of independent claim 55. Gissman fails to disclose a complex requiring an L1 interaction sequence of the instant application. The novel L1 interaction sequence was first disclosed in the instant application. Therefore, the Applicants respectfully request removal of rejections based on Gissman.

On pages 3-4, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et. al (U.S. Patent no. 6,908,613 B2) [hereinafter, “Wilson”] ...for the reasons of record ...” The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Wilson recites “A *chimeric* HPV L1 protein comprising HPV-18 L1 protein and HPV-45 L1 protein” (see independent claim 1) and “A method of treating papillomavirus caused by at least one of HPV-18 and HPV-45 comprising administering to a patient an effective amount of the [chimeric] protein of claim 1” (see claim 5 of Wilson). The Applicants respectfully submit that independent claim 55 overcomes rejections based on Wilson. Wilson fails to disclose “one or more papillomavirus capsid L1 interaction sequence(s)” are required for complexes of the instant claims, and in particular elements of independent claim 55. In addition, Wilson fails to disclose “the papillomavirus capsid L1 interaction sequence comprises at least 80% identity corresponding to amino acid sequence beginning with amino acid 396 and ending with amino acid 439 of SEQ ID NO: 1 or fragments thereof,” elements of independent claim 55. Therefore, the Applicants respectfully request removal of rejections based on Wilson.

On pages 5-6, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 102(c) as being anticipated by Hallek et. al (U.S. Patent no. 7,182,947 B2, [hereinafter, “Hallek”]) for the reasons of record...”

The Applicants submit that Hallek recites “Vaccine formulations comprising viral capsomeres are disclosed along with methods for their production...” (see Abstract). Hallek recites “A protein encoded by an...encoding a truncated HPV L1 protein... wherein said protein is immunogenic against HPV,” (see independent claim 1 of Hallek). Hallek recites in claim 2 “A protein encoded by...encoding a fusion protein, said fusion protein comprising an amino acid sequence of a truncated first HPV L1 and an amino acid sequence of a second HPV proteins...said second HPV protein is selected from the group...” The Applicants respectfully submit that independent claim 55 overcomes rejections based on Hallek. Hallek fails to disclose “one or more papillomavirus capsid L1 interaction sequence(s)” are required for complexes of the instant claims, and in particular, elements of independent claim 55. In addition, Hallek fails to disclose “the papillomavirus capsid L1 interaction sequence comprises at least 80% identity corresponding to amino acid sequence beginning with amino acid 396 and ending with amino acid 439 of SEQ ID NO: 1 or fragments thereof,” elements of independent claim 55. Therefore, the Applicants respectfully request removal of rejections based on Hallek.

### **Rejection under 35 U.S.C. §102**

#### *§102(b)*

On page 6, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Gissman et. al (U.S. Patent no. 6,228,368 B1) [hereinafter, “Gissmann2”] for the reasons of record...” The Applicants respectfully disagree with this assertion.

The Applicants respectfully submit that independent claim 55 overcomes rejections based on Gissmann2. Gissmann2 fails to disclose “one or more papillomavirus capsid L1 interaction sequence(s)” are required for complexes of the instant claims, and in particular, elements of independent claim 55. In addition, Gissman2 fails to disclose “the papillomavirus capsid L1 interaction sequence comprises at least 80% identity corresponding to amino acid sequence beginning with amino acid 396 and ending with amino acid 439 of SEQ ID NO: 1 or fragments thereof,” elements of independent claim 55. Therefore, the Applicants respectfully request removal of rejections based on Gissman2.

On page 7, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcea et. al (U.S. Patent no. 6,,165,471 A) [hereinafter, “Garcea”] for the reasons of record...” The Applicants respectfully disagree with this rejection.

The Applicants respectfully submit that Garcea recites “stable HPV capsomeres which express at least one virus-neutralizing conformational epitope of a native HPV L1 protein which are substantially capsomeres...”(see Abstract). The Applicants respectfully submit that independent claim 55 overcomes rejections based on Garcea. Garcea fails to disclose “one or more papillomavirus capsid L1 interaction sequence(s)” are required for complexes of the instant claims, and in particular elements of independent claim 55. In addition, Garcea fails to disclose “the papillomavirus capsid L1 interaction sequence comprises at least 80% identity corresponding to amino acid sequence beginning with amino acid 396 and ending with amino acid 439 of SEQ ID NO: 1 or fragments thereof,” elements of independent claim 55. Therefore, the Applicants respectfully request removal of rejections based on Garcea.

#### **Rejection under 35 U.S.C. §112**

##### *§112, second paragraph*

On page 9, the Action asserts that “Claims 55-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter...”

Claims 55 and 59 are rejected as appearing “to be essential duplicates of one another.” Claim 59 has been canceled, therefore this rejection is moot. The Applicants respectfully request removal of the rejection.

Claims 55, 61 and 62 are rejected as being ‘vague and indefinite’, because of the limitation “truncated.” The Applicants respectfully submit that claims 55, 61 and 62 have been amended to overcome the rejection based on “truncated.” (See also Appendix B, attached) Claim 55 now recites “truncated papillomavirus capsid L1 polypeptides comprise papillomavirus capsid L1 polypeptides having: a truncation up to 30 amino acids removed from a carboxy terminus, a truncation up to 9 amino acids removed from an amino terminus and point mutations at cysteines residues within the papillomavirus capsid L1 polypeptides.” Therefore, the Applicants request removal of the §112 rejections.

The Applicants respectfully submit that independent claims 55 and 73 are in condition for allowance. Because claims 56-58 and 60-72 depend from and contain all the elements of independent claim 55 plus additional elements, claims 56-58 and 60-72 are also in condition for allowance.

**CONCLUSION**

For at least the reasons stated above, the Applicants respectfully submit that claims 55-58 and 60-73 are in condition for allowance. Please feel free to call the undersigned, if additional response is required.

Respectfully submitted,

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